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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 99.45 US

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on October 5, 2006

Signature: Maria Anzaldi

Typed or printed name: Maria Anzaldi

Application Number	Filed
09/554,984	05/23/2000

First Named Inventor: Maes et al.

Art Unit	Examiner
1616	Alton Pryor

Applicant requests review of the claim rejections in the August 11, 2006 Office Action in the above-identified Application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☐ attorney or agent of record. Registration number _____
- ☒ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34: 56,310

Signature

Yongzhi Yang
Typed or printed name

631-414-6089
Telephone number

October 5, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 2 forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Maes, et al.	Examiner:	Alton Pryor
Serial No:	09/554,984	Art Unit:	1616
Filed:	May 23, 2000	Docket:	99.45US
For:	COMPOSITION FOR IMPROVING SKIN LIPID BARRIER FUNCTION	Dated:	October 5, 2006

Confirmation No.: 1797

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

This is submitted in support of the Pre-Appeal Brief Request for Review Form, which is filed concurrently herewith. Applicant hereby request a pre-appeal brief panel review of the claim rejections in the August 11, 2006 Office Action.

In the August 11, 2006 Office Action, the Examiner rejected claims 15 and 28 under 35 U.S.C. §103(a) as allegedly obvious over U.S. Patent No. 5,932,234 to Simon et al. ("Simon").

Claim 15, from which claim 28 depends, positively recites a composition for topical application to the skin comprising: (1) from 0.001 to 10% of at least one protease inhibitor, which can be, *inter alia*, asiatic acid, (2) from 0.001 to 10% of at least one cell differentiation enhancer, which can be, *inter alia*, vitamin D3 analogs, and (3) a self tanning agent, which is DHA.

Simon does not disclose any specific composition comprising a protease inhibitor, a cell differentiation enhancer and a self tanning agent. Instead, Simon discloses in general a cosmetic and/or dermatological composition comprising: (i) at least 20% by weight of a fatty phase, (ii) at least one fatty ester of a C_5-C_7 carbohydrate, (iii) at least one polyol, and (iv) at least one cosmetic and/or dermatological active agent (see Simon, column 1, lines 63-67 and column 2, lines 1-2). At column 5, lines 66-67 and column 6, lines 1-38, Simon provides a laundry list of about sixty (60) compounds or families of compounds that can be used as the

cosmetic/dermatological active agent, including:

1. ascorbic acid and esters thereof,
2. allantoin, citric acid,
3. caffeic acid,
4. salicylic acid and its derivatives,
5. lactic acid,
6. methyllactic acid,
7. glucuronic acid,
8. glycolic acid,
9. pyruvic acid,
10. 2-hydroxybutanoic acid,
11. 2-hydroxypentanoic acid,
12. 2-hydroxyhexanoic acid,
13. 2-hydroxyheptanoic acid,
14. 2-hydroxyoctanoic acid,
15. 2-hydroxynonanoic acid,
16. 2-hydroxydecanoic acid,
17. 2-hydroxyundecanoic acid,
18. 2-hydroxydodecanoic acid,
19. 2-hydroxytetradecanoic acid,
20. 2-hydroxyhexadecanoic acid,
21. 2-hydroxyoctadecanoic acid,
22. 2-hydroxytetra-ecosanoic acid,
23. 2-hydroxyeicosanoic acid and
24. mandelic acid,
25. benzoic acid,
26. phenyllactic acid,
27. gluconic acid,
28. galacturonic acid,
29. aleuritic acid,
30. ribonic acid,
31. tartronic acid,
32. tartaric acid,
33. malic acid,
34. fumaric acid,
35. retinoic acid and its derivatives,
36. benzene-1,4-bis(3-methylidene-10-camphorsulphonic acid),
37. **dihydroxyacetone (DHA),**
38. water-soluble vitamins,
39. starch,
40. bacterial or plant extracts,
41. tocopherol (vitamin E) and its derivatives,
42. essential fatty acids,
43. ceramides,
44. essential oils
45. plant proteins and their hydrolysates,
46. xanthic derivatives (caffeine, theophylline),
47. beta.-glycyrrhetinic acid,
48. **asiatic acid,**
49. octopirox,
50. retinol and its esters,
51. natural derivatives of the flavonoid family,
52. **vitamin D and its derivatives,**
53. oestradiol,
54. kojic acid,
55. hydroquinone;
56. alpha.-tocopherol or its esters,
57. superoxide dismutases,
58. certain metal-chelating agents;
59. antagonists of substance P and/or of CGRP (calcitonin gene related peptide) such as Iris pallida and strontium salts, and
60. antagonists of substance P and/or of CGRP such as those described in French patent applications FR-A-2,719,474 and FR-A-2,729,855.

In the August 11, 2006 Office Action, the Examiner asserted that "*it would have been obvious to one having ordinary skill in the art to make such an invention*" that specifically combines DHA (No. 37), asiatic acid (No. 48), and vitamin D and its derivatives (No. 52) from this list, and that "*Simon suggests the combination*" (see Office Action, page 2, lines 19-20).

Applicants respectfully disagree, for the following reasons:

It has been well established that when prior art discloses many possible choices without giving any direction or guidance as to which of these many possible choices is likely to be successful, the prior

art constitutes at most a suggestion that it would be "**obvious to try**" each of numerous possible choices until one possibly arrived at a successful result, which is **insufficient for supporting *a prima facie* case of obviousness** under 35 U.S.C. §103. See In re Geiger, 815 F.2d 686 (Fed. Cir. 1987); Novo Industri A/S v. Travenol Laboratories, Inc., 677 F.2d 1202 (7th Cir. 1982).

In the present case, nothing in Simon teaches or suggests a composition that specifically combines the above-identified three (3) compounds, i.e., DHA, asiatic acid, and vitamin D and derivatives thereof (as expressly conceded by the Examiner in the August 11, 2006 Office Action on page 2, lines 18-19). Simon only discloses selection of active agents from the above-listed sixty (60) compounds or families of compounds, which can lead to **trillions of different combinations**. For example, for compositions containing three (3) compounds out of the sixty (60) compounds, the total number of possible combinations is C(60,3) = 34,220; for compositions containing five (5) out of the sixty (60) compounds, the total number is C(60,5) = 5,461,512; and for compositions containing thirty (30) out of the sixty (60) compounds, the total number is C(60,30) = 118,264,581,564,861,420 (calculated by the Combination Calculator at *http://fclass.vaniercollege.qc.ca/web/mathematics/real/Calculators/PermsCombs_Calc_1.htm*, visited on September 29, 2006). Simon does not provide any direction or guidance as to which of these trillions of combinations is likely to be successful in achieving a particular result. In absence of such direction or guidance, one ordinarily skilled in the art would have to try each of these trillions of combinations to find out which could achieve a contemplated result.

The present invention, by specifically combining a protease inhibitor and a cell proliferation enhancer with a self tanning agent, achieves **an unexpected and surprising result**, i.e., enhancing and prolonging a self-applied tan (see instant specification, page 9, lines 23-34 and page 10, lines 1-8). Such an unexpected and surprising result was not appreciated, recognized, or even contemplated in any manner by Simon.

Further, the composition recited by claims 15 and 28 of the present application is suitable to be applied to and left on the skin, while the compositions disclosed by Simon are rinsable products intended only for a short period of application followed by rinsing (see Simon, column 1, lines 54-55).

Therefore, Simon does not support a *prima facie* case of obviousness against claims 15 and 28 of the present application.

In the August 11, 2005 Office Action, the Examiner rejected claims 2, 6, 8, 16, 17, 20, 23, 26, 33, and 36 under 35 U.S.C. §103(a) as allegedly obvious over Simon in view of U.S. Patent No. 6,150,381 to Subbiah et al. ("Subbiah"). Specifically, the Examiner asserted that Simon teaches all the limitations of claims 2, 6, 8, 16, 17, 20, 23, 26, 33, and 36, except for sclareolide, and that it would be obvious to modify the invention of Simon to include the sclareolide disclosed by Subbiah.

Applicants respectfully disagree with the Examiner, for the following reasons:

Claim 6, from which claims 2, 8, 16, 17, 20, 23, and 36 depend, recites a composition comprising: (1) from 0.001 to 10% of at least one protease inhibitor, and (2) from 0.001 to 10% of at least one cell differentiation enhancer, which is sclareolide.

Simon does not disclose any specific composition comprising a protease inhibitor and a cell differentiation enhancer. The general disclosure by Simon about selection of active agents from the above-listed sixty (60) compounds or families of compounds, as mentioned hereinabove, can lead to **trillions of different combinations**.

Subbiah only discloses the use of sclareolide for treating microbal infection (see Subbiah, column 3, lines 20-27). Nothing in Subbiah teaches or suggests the use of sclareolide in combination with a protease inhibitor.

Therefore, the combination of Subbiah with Simon, as suggested by the Examiner in the August 11, 2006, would also lead to trillions of different combinations, each of which contains the sclareolide disclosed by Subbiah and certain compounds selected from the sixty (60) compounds or families of compounds disclosed by Simon. Since neither Subbiah nor Simon provides any direction or guidance that would motivate a person ordinarily skilled in the art to form the specific composition recited by claims 2, 6, 8, 16, 17, 20, 23, and 36 of the present application, the combination of Subbiah and Simon is still insufficient for establishing a *prima facie* case of obviousness against claims 2, 6, 8, 16, 17, 20, 23, and 36.

The Examiner also rejected claim 10 under 35 U.S.C. §103(a) as allegedly obvious over the combination of Simon and U.S. Patent No. 5,885,565 to Elias et al. (hereinafter "Elias"). Specifically, the Examiner asserted that Simon teaches all the limitations recited by claim 10 except for cholesterol and that it would be obvious to modify the invention of Simon to include the cholesterol sulfate disclosed by Elias.

Applicants respectfully disagree, for the following reasons

Claim 10, from which claims 29 and 30 depend, recites a composition comprising: (1) from 0.001 to 10% of at least one protease inhibitor, which is cholesterol sulfate, and (2) from 0.001 to 10% of at least one cell differentiation enhancer.

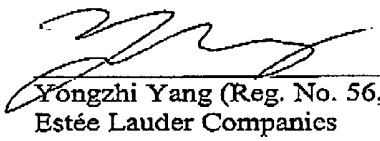
As mentioned hereinabove, Simon does not disclose any specific composition comprising a protease inhibitor and a cell differentiation enhancer, and the general disclosure by Simon about selection of active agents from the above-listed sixty (60) compounds or families of compounds can lead to **trillions of different combinations**.

Elias only discloses the application of cholesterol sulfate to skin to enhance penetration through the epithelium of a host (see Elias, claim 1). Nothing in Elias teaches or suggests the use of cholesterol sulfate in combination with a cell differentiation enhancer.

Therefore, the combination of Elias with Simon, as suggested by the Examiner in the August 11, 2006, would also lead to trillions of different combinations, each of which contains the cholesterol sulfate disclosed by Elias and certain compounds selected from the sixty (60) compounds or families of compounds disclosed by Simon. Since neither Elias nor Simon provides any direction or guidance that would motivate a person ordinarily skilled in the art to form the specific composition recited by claims 10, 29, and 30 of the present application, the combination of Elias and Simon is still insufficient for establishing a *prima facie* case of obviousness against claims 10, 29, and 30.

Based on the foregoing, Applicants submit that the §103 claim rejections as raised by the Examiner in the August 11, 2006 are clearly improper. Correspondingly, Applicants request the panel to review such claim rejections prior to the filing of an Appeal Brief by Applicants.

Respectfully submitted,



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